DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
D1437B

60 8th Street, N.E.
Atlanta, Georgia 30309

February 23, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Carol Pouling
Office Manager
Northside - Alpharetta Imaging
3400-A State Bridge Road
Suite 160
Alpharetta, GA 30202

WARNING LETTER

Dear Ms. Pouling:

Your facility was inspected on 2/17/98 by the Georgia Department of Human Resources under contract to the Food and Drug Administration. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography as specified in Title 21 Code of Federal Regulations (CFR), Part 900.12, as follows:

> The interpreting physician did not meet the continuing education requirements of having completed a minimum of 15 credits in mammography over a 3-year period (an average of 5 credits/year) [redacted]

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 3 deficiency that was listed on the inspection report provided to you at the close of the inspection. The Level 3 noncompliance is as follows:

> The chest wall edge of the compression paddle was visible on the collimation test image obscuring part of the area of clinical interest: GE MEDICAL SYSTEMS SENOGRAPHE 600 T; rm 2.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirement, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper recordkeeping procedures, if the noncompliances that were found relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted.)

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to:

U.S. Food and Drug Administration
Compliance Enforcement
60 8th Street, N.E.
Atlanta, Georgia 30309

With a copy to:

Georgia Department of Human Resources
Diagnostic Services Section
2 Peachtree Street
Atlanta, GA 30303-3124

You may choose to address both FDA and State requirements in your response. If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call John J. McCall at (404) 347-3162.

Sincerely yours,

Ballard H. Graham, Director
Atlanta District